

CLAIMS

We claim:

1. A pharmaceutical composition comprising of
  - 5 A) a slow release therapeutic agent as one of components
  - B) another slow or immediate release therapeutic agent belonging to a class of drugs not similar to the one covered under component A
  - C) a slow or immediate release therapeutic agent belonging to a class of drugs not similar to the ones covered under either A or B
- 10 Wherein the triple combination uses drugs prescribed, for a particular disorder and its related maladies by the physicians, acting either by different or by same mechanism of action.
2. A pharmaceutical composition of claim 1 wherein the disorder is either diabetic and its associated disorders or cardiovascular and its associated disorders.
3. The pharmaceutical composition of claim 1 wherein the component A is a biguanide the
  - 15 component B is sulfonylurea and the component C is a Glitazone.
4. A pharmaceutical kit containing the agents as defined in claim 1 either as single or as dual or as triple entities for administration to humans suffering from diabetes and its associated disorders.
5. A pharmaceutical kit containing the agents as defined in claim 1 either as single or as dual or
  - 20 as triple entities for administration to humans suffering from cardiovascular and its associated disorders.
6. A pharmaceutical kit of claim 3 wherein the agents are consumed within 0-12 hours after ingestion of any of the other two therapeutic agents.
7. A method of treatment using a pharmaceutical composition of claim 1, which when ingested
  - 25 by humans
  - a) Reduces the Cmax by at least 10-15 % for the slow release component relative to the corresponding immediate release component.
  - b) Increases the Tmax by at least about 20-30 % for the slow release component relative to the corresponding immediate release component.

c) While having an insubstantial effect on the area under the plasma concentration time curve (AUC) of the dose of the slow release component relative to the corresponding immediate release component.

8. A therapeutically effective amount of a pharmaceutical composition of claim 1 which allows  
5 a reduction in the dosing regimen of any one of the individual agents.

9. The pharmaceutical composition of claim 1 in the form of one or more tablets.

10. The pharmaceutical composition of claim 1 in the form of one or more capsules.

11. The pharmaceutical composition of claim 1 wherein the components are physically separated

12. The pharmaceutical composition of claim 1 wherein when tested for in-vitro release, around  
10 30-50% of the slow release component(s) is released within a period of about 2 to 3 hours  
and not less than 75% of the slow release component(s) released within a period maximum  
24 hours.

13. A pharmaceutical composition of claim 1 wherein at least one or two of the slow release  
components released via a composition by virtue of its gastro-retention mechanism.

14. The pharmaceutical composition of claim 1 wherein the component A is a biguanide the  
15 component B is an ACE inhibitor and the component C is Aspirin

15. The pharmaceutical composition of claim 1 wherein the component A is a biguanide the  
component B is Aspirin and the component C is an ACE inhibitor.

16. The pharmaceutical composition as defined in claim 14 wherein the component A is a  
20 metformin the component B is Aspirin and the component C is Ramipril.

17. A pharmaceutical kit containing the agents as defined in claim 16 either as single or dual or  
as triple entities for administration to humans suffering from diabetes and its associated  
disorders.

18. A pharmaceutical kit containing the agents as defined in claim 16 either as single or dual or  
25 triple entities for administration to humans suffering from cardiovascular and its associated  
disorders with or without diabetes.

19. A pharmaceutical kit as defined in claim 16 wherein the agents are consumed within 0-12  
hours after ingestion of any of the other two therapeutic agents.

20. A method of treatment using a pharmaceutical composition as defined in claim 16 which  
30 when ingested by human

a) Reduces the Cmax by at least 10-15 % for the slow release component relative to the

corresponding immediate release component.

b) Increases the T<sub>max</sub> by at least about 20-30 % for the slow release component relative to the corresponding immediate release component.

c) While having an insubstantial effect on the area under the plasma concentration time  
5 curve (AUC) of the dose of the slow release component relative to the corresponding immediate release component.

21. A therapeutically effective amount of a pharmaceutical composition of claim 16 which allows a reduction in the dosing regimen of any of the individual agents for diabetic and its associated disorders.

10 22. A therapeutically effective amount of a pharmaceutical composition of claim 16 which allows a reduction in the dosing regimen of any of the individual agents for cardiovascular and its associated disorders.

23. The pharmaceutical formulation as defined in claim 16 in the form of one or more tablets.

24. The pharmaceutical formulation as defined in claim 16 in the form of one or more capsules.

15 25. The pharmaceutical formulation as defined in claim 16 in the form of one or more tablets and /or capsules.

26. The pharmaceutical composition of claim 16 wherein when tested for in-vitro release, around 30-50% of the drug is released for the slow release component within a period of about 2 to 3 hours and not less than 75% of the drug is released within a period maximum 24 hours.

20 27. A method of treating a disease with a pharmaceutical composition of claim 16 comprising administering a human in need of treatment for the said disease.

28. The pharmaceutical composition of claim 1 wherein the component A is a nitrate the component B is platelet inhibitor and the component C is an HMG-CoA inhibitor

25 29. The pharmaceutical composition of claim 28 wherein the component A is isosorbide mononitrate the component B is clopidogrel / aspirin and the component C is statin.

30. A pharmaceutical kit containing the agents as defined in claim 28 either as single or dual or triple entities for administration to humans suffering from hypertensive and its associated disorders.

30 31. A pharmaceutical kit containing the agents as defined in claim 28 either as a single or dual or triple entities for administration to humans suffering from cardiovascular and its associated disorders.

32. A pharmaceutical kit containing the agents as defined in claim 28 either as a single or dual or triple entities for administration to humans suffering from hyperlipidemia and its associated disorders.
33. A pharmaceutical kit as defined in claim 28 wherein the agents are consumed within 0-12 hours after ingestion of any of the other two therapeutic agents.
34. The pharmaceutical composition as defined in claim 28 which when ingested by human
- a) reduces the  $C_{max}$  by at least 10-15 % for the slow release component relative to the corresponding immediate release component
  - b) increases the  $T_{max}$  by at least about 20-30 % for the slow release components relative to the corresponding immediate release component
  - c) while having an insubstantial effect on the area under the plasma concentration time curve (AUC) of the dose of the slow release component relative to the corresponding immediate release component.
35. A therapeutically effective amount of a pharmaceutical formulation of claim 28 which allows a reduction in the dosing regimen of any one of the individual agents for patients with hypertension and its associated disorders.
36. A therapeutically effective amount of a pharmaceutical formulation of claim 28 which allows a reduction in the dosing regimen of any one of the individual agents for patients with cardiovascular and its associated disorders.
37. A therapeutically effective amount of a pharmaceutical formulation of claim 28 which allows a reduction in the dosing regimen of any one of the individual agents for patients with hyperlipidemic and its associated disorders
38. The pharmaceutical formulation as defined in claim 28 in the form of one or more tablets.
39. The pharmaceutical formulation as defined in claim 28 in the form of one or more capsules.
40. The pharmaceutical formulation as defined in claim 28 in the form of one or more tablets and /or capsules.
41. The pharmaceutical composition as defined in claim 28 wherein when tested for in-vitro release, around 30-50% of the drug is released for the slow release component within a period of about 2 to 3 hours and not less than 75% of the drug is released within a period maximum 24 hours.

42. A method of treating a disease with a pharmaceutical composition of claim 28 comprising administering a human in need of treatment for the said disease.
43. The pharmaceutical composition of claim 1 wherein the component A is a calcium channel blocker, the component B is beta-blocker and the component C is an HMG-CoA inhibitor
- 5 44. The pharmaceutical composition as defined in claim 43 wherein the component A belongs to 1,4-dihydropyridines, the component B is beta blocker and the component C is a statin.
45. The pharmaceutical composition as defined in claim 43 wherein the component A is Nifedipine, the component B is atenolol and the component C is atorvastatin.
46. A pharmaceutical kit containing the agents as defined in claim 43 either as single or dual or  
10 triple entities for administration to humans suffering from cardiovascular and its associated disorders.
47. A pharmaceutical kit containing the agents as defined in claim 43 either as single or dual or triple entities for administration to humans suffering from hyperlipidemic and its associated disorders.
- 15 48. A pharmaceutical kit as defined in claim 43 wherein the agents are consumed within 0-12 hours after ingestion of any of the other two therapeutic agents.
49. The pharmaceutical composition as defined in claim 43 which when ingested by human
  - a) reduces the C<sub>max</sub> by at least 10-15 % for the slow release component relative to the corresponding immediate release component
  - 20 b) increases the T<sub>max</sub> by at least about 20-30 % for the slow release component relative to the corresponding immediate release component
  - c) while having an insubstantial effect on the area under the plasma concentration time curve (AUC) of the dose of the slow release component relative to the corresponding immediate release component.
- 25 50. A therapeutically effective amount of a pharmaceutical formulation of claim 43 which allows a reduction in the dosing regimen of any one of the individual agents for patients with cardiovascular and its associated disorders.
51. A therapeutically effective amount of a pharmaceutical formulation of claim 43 which allows a reduction in the dosing regimen of any one of the individual agents for patients with  
30 hyperlipidemic and its associated disorders.
52. The pharmaceutical formulation as defined in claim 43 in the form of one or more tablets.

53. The pharmaceutical formulation as defined in claim 43 in the form of one or more capsules.
54. The pharmaceutical formulation as defined in claim 43 in the form of one or more tablets and /or capsules.
55. The pharmaceutical composition as defined in claim 43 wherein when tested for in-vitro  
5 release, around 30-50% of the drug is released for the slow release component within a period of about 2 to 3 hours and not less than 75% of the drug is released within a period maximum 24 hours.
56. A method of treating a disease with a pharmaceutical composition of claim 43 comprising administering a human in need of treatment for the said disease.
- 10 57. The pharmaceutical composition of claim 1 wherein the component A is a calcium channel blocker, component B is an angiotensin receptor antagonist and the component C is an HMG-CoA inhibitor
58. The pharmaceutical composition as defined in claim 57 wherein the component A is a 1,4 dihydropyridine, the component B is a sartan and the component C is a statin.
- 15 59. The pharmaceutical composition as defined in claim 57 wherein the component A is a Nifedipine, the component B is losartan and the component C is atorvastatin.
60. A pharmaceutical kit containing the agents as defined in claim 57 either as single or dual or triple entities for administration to humans suffering from hypertension and its associated disorders.
- 20 61. A pharmaceutical kit containing the agents as defined in claim 57 either as single or dual or triple entities for administration to humans suffering from cardiovascular and its associated disorders.
62. A pharmaceutical kit containing the agents as defined in claim 57 either as single or dual or triple entities for administration to humans suffering from hyperlipidemic and its associated  
25 disorders.
63. A pharmaceutical kit as defined in claim 57 wherein the agents are consumed within 0-12 hours after ingestion of any of the other two therapeutic agents.
64. The pharmaceutical composition as defined in claim 57 which when ingested by human  
30 a) reduces the C<sub>max</sub> by at least 10-15 % for the slow release component relative to the corresponding immediate release component.  
b) increases the T<sub>max</sub> by at least about 20-30 % for the slow release component relative to

the corresponding immediate release component

c) while having an insubstantial effect on the area under the plasma concentration time curve (AUC) of the dose of the sustained / controlled / extended release components relative to the corresponding immediate release component.

- 5 65. A therapeutically effective amount of a pharmaceutical formulation of claim 57 which allows a reduction in the dosing regimen of any one of the individual agents for patients with hypertension and its associated disorders.
66. A therapeutically effective amount of a pharmaceutical formulation of claim 57 which allows a reduction in the dosing regimen of any one of the individual agents for patients with
- 10 cardiovascular and its associated disorders.
67. A therapeutically effective amount of a pharmaceutical formulation of claim 57 which allows a reduction in the dosing regimen of any one of the individual agents for patients with hyperlipidemic and its associated disorders.
68. The pharmaceutical formulation as defined in claim 57 in the form of one or more tablets.
- 15 69. The pharmaceutical formulation as defined in claim 57 in the form of one or more capsules.
70. The pharmaceutical formulation as defined in claim 57 in the form of one or more tablets and / or capsules.
71. The pharmaceutical composition as defined in claim 57 wherein when tested for in-vitro release, around 30-50% of the drug is released for the slow release component within a
- 20 period of about 2 to 3 hours and not less than 75% of the drug is released within a period maximum 24 hours.
72. A method of treating a disease with a pharmaceutical composition of claim 57 comprising administering a human in need of treatment for the said disease.